REMARKS

A. Amendments in the specification

Insertion of a new paragraph on page 1 is requested to provide cross-reference to a copending application having related subject matter.

Paragraphs on pages 1–2 are amended to replace "WO 94/07568" with "WO 94/07468" in order to correct a typographical error.

The paragraph bridging pages 1 and 2 is amended to delete discussion therein of a cited background reference (International Patent Publication No. WO 99/49852) to avoid any possibility of that discussion being potentially construed as mischaracterizing the disclosure of WO 99/49852. To the extent that any part of the wording of the now-deleted passage could be construed as mischaracterizing in any manner the disclosure of WO 99/49852, such wording was inadvertent and without deceptive intent, and Applicant invites the Examiner to read WO 99/49852 to determine what is disclosed therein.

Paragraphs on page 3 and bridging pages 9 and 10 are amended to be in alignment with Claim 1 as amended herein. As explanation of these amendments, see the remarks below relating to amendment of Claim 1.

B. Amendments in the claims

The following claims are now pending in the present application: Claims 1–7.

Claim 1 is amended to recite that the self-adhesive matrix "comprises" rather than "consists of" a solid or semi-solid polymer as further defined in the body of the claim. This amendment from language that could be construed as "closed" to explicitly open-ended language is made in the interests of clarity and finds support throughout the specification as filed. For example, although the matrix in "a particularly preferred embodiment" is described at page 9, lines 21–31 as being free of particles such as silica particles, it is implicit in this description (and by differentiation of Claim 3 over Claim 1) that the TDS can, in its broadest embodiment, have such particles in the matrix. Further, the specification at page 12, lines 1–12 describes "a further preferred embodiment" wherein the TDS "further includes a crystallization inhibitor". That a crystallization inhibitor (*e.g.*, polyvinylpyrrolidone) can be present as an additional component of the matrix (as opposed to the backing layer or

removable protective sheet) is clear at least from the description of Invention Example 1, especially at page 14, lines 11–25. This description also shows that other materials can be present in the matrix, such as sodium bisulfite, ascorbyl palmitate and DL-α-tocopherol. The original use of "consisting of" language in Claim 1 and in various passages of the specification was an inadvertent error, made without deceptive intent, it being clear from the specification as a whole that other optional ingredients could be included in the matrix.

Claim 1 is further amended to clarify that the multitude of microreservoirs optionally contain one or more components in addition to the rotigotine, one such optional component being a crystallization inhibitor. Support for a crystallization inhibitor as an optional component of the microreservoirs is found in the specification as filed, at least at page 6, lines 9–10.

Claim 1 is still further amended to remove the recitation that the matrix is saturated with rotigotine. As stated in the specification at page 5, line 36 – page 6, line 5, the presence of rotigotine in microreservoirs within the matrix "does not exclude and will normally even imply that a certain fraction of rotigotine is dissolved in the ... matrix at its saturation concentration." In other words, it is likely, but not certain or essential, that the matrix is saturated with rotigotine.

Claim 1 is still further amended to remove the adverb "highly" as a qualifier of "permeable" and to insert the adverb "substantially" as a qualifier of "impermeable". One of skill in the art reading the specification as a whole will understand (a) that the degree of permeability to the free base form of rotigotine is merely sufficient to provide acceptable flux – see, for example, the specification as filed at page 9, lines 16–17; and (b) that "impermeable" is not to be construed in an absolute sense, particularly in light of the disclosure in the specification as filed at page 6, lines 16–22, that some residual amount of rotigotine in salt form can be present in the matrix.

Claims 1–5 are amended to replace "characterized in that" or "characterized in" with "wherein", to present these claims in a form more in accordance with standard U.S. claim drafting practice.

Claims 4–6 are amended to delete the word "type" appended to "silicone", to further

enhance clarity of these claims without affecting the meaning or scope of the claims.

Opportunity has been taken, in amending the claims, to correct typographical errors, to rephrase where it has been desirable to do so for enhanced clarity, and to present subject matter where necessary in terms more in accordance with standard U.S. claim drafting practice.

No new matter is added, and no change in inventorship is believed to result from amendment of the claims as proposed herein.

RESPONSE TO OFFICE ACTION DATED DECEMBER 7, 2006

1. Restriction Requirement

By the present Action, Applicant is required under 35 U.S.C. §121 to restrict the application to one of the following inventions:

I. Claims 1–6.

II. Claim 7.

Applicant provisionally elects with traverse the invention of Group I, embodied in Claims 1–6 which are drawn to a transdermal delivery system (TDS). Applicant notes that where restriction has been made between product and process claims, as in the present Action, and product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of an allowable product claim will be eligible for rejoinder. The present restriction requirement is traversed at least on grounds set forth below, none of which constitutes admission that the inventions of Groups I and II are not patentably distinct.

The subject matters of Groups I and II, while patentably distinct, are sufficiently closely related not to impose an undue search burden on the Examiner. Applicant disagrees with the characterization of Groups I and II in the present Action as encompassing "divergent subject matter" requiring searching of "extensive databases of patent and non-patent literature". . A search for application to skin of a rotigotine-containing TDS to treat a rotigotine-treatable disease needs no more extensive databases than a search for the rotigotine-containing TDS itself.

2. Election of Species

By the present Action, Applicant is further required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits, to which the claims shall be restricted if no generic claim is finally held to be allowable. By provisional election herein, Applicant makes no admission that the invention is limited to the elected species.

Applicant provisionally elects with traverse a species as set forth in Claim 6, namely a TDS as defined in Claim 1 wherein the self-adhesive matrix comprises two or more silicone-type pressure sensitive adhesives including a high-tack and a medium-tack silicone-type adhesive, each comprising a polysiloxane with a resin. This species can be seen to conform to species (a), subspecies (2) as proposed in the present Action, pages 3–4, and species (1) as proposed in the present Action, page 5.

The requirement for election of species is traversed on the ground that individual species embraced by generic claims such as Claim 1, while patentably distinct, are sufficiently closely related not to impose an undue search burden on the Examiner. Claim 1 sets forth five characteristics of the self-adhesive matrix, which functionally define the transdermal delivery system (TDS) as presently claimed. The particular species identified in the present Action represent embodiments of the TDS having these five characteristics.

Applicant assumes the references in the Action at page 5 to the "undue search burden that will be created by the multiplicity of tumor, viral and bacterial cells encompassed by these claims" and at page 6 to "claims 1, 27, 28, 29, 30, 31, 38, 39, 42, 43 and 44" which are "considered generic" are inadvertently and erroneously presented therein, and that the present response will be considered complete without addressing these further.

Respectfully submitted,

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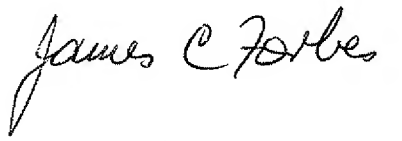

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